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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Andrew Thomas Forsberg

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EXAMINER

COLELLO, ERIN L

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/713,530	Applicant(s) FORSBERG ET AL.	
	Examiner ERIN COLELLO	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,13-16,20,21,28,45-49,51-54 and 57-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,13-16,20,21,28,45-49,51-54 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on July 7, 2009. The amendment after final received on June 22, 2009 will be considered. Claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 will be prosecuted on the merits.

Applicant's arguments with respect to claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 have been considered but are moot in view of the new ground of rejection.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 uses "drip hole" which is vague and indefinite because it is not fully understood what is meant by the term "drip hole" and the specification does not provide guidance as to how to interpret what is meant by "drip hole". For the purpose of examination, the Examiner is interpreting "drip hole" to refer to a port that allows fluid to flow out of the opening. Correction is needed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

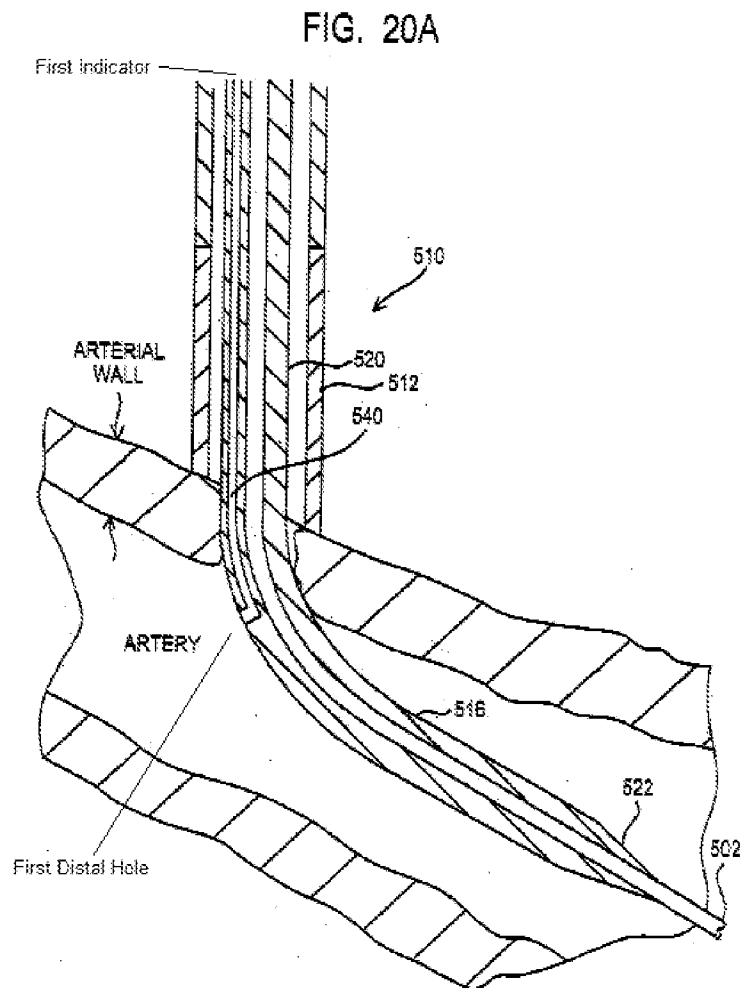
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims **1, 13-16, 20, 28, 45-49, 51-54 and 57-59**, are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kanner et al. (US 6,767,356 B2)**.

Regarding claims 1, 20, 28, 45-49, 52, 53, 54, 57, 58 and 59, Kanner discloses a vascular insertion assembly, comprising: an insertion sheath having a distal end and a proximate end (Ref 512); a dilator having a distal end and a proximate end sized to fit inside the insertion sheath (Ref 520), the dilator having a distal end positionable distally beyond a distal end of the insertion sheath (Ref 516); a first distal hole located in the distal end of the dilator such that the first distal hole is positionable distally beyond the distal end of the insertion sheath, the first distal hole being open for fluid flow only after being positioned distally beyond the distal end of the insertion sheath; wherein the first distal hole is a first inlet port (Figure 20A see below; Figures 38, 39); a first indicator located at a proximal end of the dilator (Column 8, Lines 37-50; wherein the proximal end of the blood marking lumen is a first indicator that indicates the position of the insertion assembly to the user), the first indicator being in fluid communication with the first distal hole so that when the first distal hole (inlet port) penetrates a vessel, the first indicator (outlet port) at the proximal end indicated an initial penetration of the vascular insertion assembly into the vessel at a first depth (Ref 540; wherein a lumen in the

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dilator provides the fluid communication that indicates to the user the depth; Column 8, Lines 37-50); a second distal hole located in the distal end of the insertion sheath (Figures 33 and 34, (674); wherein the second distal hole is a second inlet port also known as an over insertion hole (Column 18, Lines 60-67; Column19, Lines 1-31); and a second indicator located at a proximal end of the insertion sheath; wherein the second indicator is a second proximal hole also known as an outlet port of an over insertion indicator (Ref 684; Column 18, Lines 60-67; Column19, Lines 1-31), the second indicator being in fluid communication with the second distal hole so that when the second distal hole (inlet port) penetrates the vessel, fluid flows out of the second indicator at the proximal end and indicates that the vascular insertion assembly is at another depth in the vessel; wherein the second depth represents an over insertion of the vascular insertion assembly into the vessel (Ref 689A; Column 8, Lines 50-60; Column 18, Lines 55-67; Column 19, Lines 1-31; wherein a lumen in the insertion sheath provides the fluid communication between the second distal hole and the second indicator), wherein the second distal hole is proximally spaced apart from the first distal hole in a lengthwise direction of the vascular insertion assembly (Figure 20A; Ref 674; wherein Kanner discloses that he second distal hole and second lumen structure can be incorporated into any of the other introducer embodiments; therefore the first distal hole which is located on the distal end of the dilator which is positioned distally beyond the distal end of the sheath would be spaced apart for a second distal hole on the distal end of the sheath)



Kanner discloses all of the claimed limitations above but fails to explicitly disclose that the proximal end of the blood marking lumen is a hole or outlet port; where fluid can flow out.

However, in an alternate embodiment, Kanner teaches that the proximal end of a blood marking lumen in the sheath comprises a port for observing the presence of blood due to the proximal end entering a vessel (Column 18, Lines 55-65; Column 19, Lines 1-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal end of the first blood marking lumen to include a hole or port as taught by Kanner in Figures 33 and 34, since such a modification provides an easy way for the user to observe the presence of blood and determine the position of the insertion instrument.

Regarding claim 13, Kanner discloses that at least one of the first indicator or the second indicator is a drip hole (Ref 684; Column 18, Lines 55-67; Column 19, Lines 1-31).

Regarding claim 14, Kanner discloses a first lumen that provides the fluid communication between the first distal hole and the first indicator; wherein the first lumen passes through the dilator (Ref 540; 520).

Regarding claims 15 and 16, Kanner discloses a second lumen that provides the fluid communication between the second distal hole and the second indicator; wherein the second lumen passes through the dilator (column 8, Lines 50-60; wherein the additional blood marking passageway can be on the dilator of the distal end of the sheath).

Regarding claim 51, Kanner discloses a third distal hole is located at the distal end of the vascular insertion assembly (Ref 675) and a third indicator is located at the proximal end of the vascular insertion assembly (Ref 688), the third distal hole being in fluid communication with the third indicator (Ref 689 B; Column 8, Lines 50-60; Column 18, Lines 55-67).

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5. Claims 21 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kanner et al. (US 6,767,356 B2)** in view of **Ginn et al. (US 6,626,918 B1)**.

Regarding claim 21, Kanner discloses all of the claimed limitations above but fails to explicitly disclose a lumen having a first flow path and a second flow path; wherein the first flow path provides the fluid communication between the first distal hole and the first indicator; and the second flow path provides the fluid communication between the second distal hole and the second indicator.

However, Ginn teaches that it is well known in the art that vascular insertion assembly can include a lumen having a first flow path (Figure 17A, 651, 652, 653) and a second flow path (Figure 17A, (650, 648, 644); wherein the first flow path provides the fluid communication between the first distal hole and the first indicator (Figure 17A, 651, 652, 653); and the second flow path provides the fluid communication between the second distal hole and the second indicator (Figure 17A, (650), (648), (644); wherein both the first flow path and the second flow path are within the central lumen of the sheath).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the vascular insertion assembly to have a lumen with first and second flow paths as taught by Ginn, since such a modification allows the interior instrument to rotate in order to allow some ports to be obstructed while allowing fluid to enter other ports.

Regarding claim 60, Kanner discloses all of the claimed limitations above including that the second inlet port and the second outlet port are in fluid communication

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by way of a lumen that passes through the insertion sheath but fails to explicitly disclose that that the first inlet port and the first outlet port can be in fluid communication by way of a lumen that passes through the insertion sheath.

However, Ginn teaches that it is well known in the art for indicators of a vascular insertion assembly to be in fluid communication by way of a lumen that passes through the insertion sheath (Figure 16A-B, (550), (648), (544)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first indicator and the first lumen to pass through the insertion sheath as taught by Figures 16A-B of Ginn, since such a modification makes it easier to distinguish between the two visual indicators.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include two indicators and two lumens passing through the insertion sheath, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 have been considered but are moot in view of the new ground of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734